UTILITY OF REAL-WORLD DATA COLLECTION TOOLS FOR ASSESSING MEDICAL DEVICE BENEFITS

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Background

- For many medical devices the evidence of efficacy and safety is limited compared to pharmaceuticals[1]
- Typical high quality evidence generation through randomized controlled trials is often not feasible for medical devices[2]
- This can be overcome by real-world data collected during device use
- Here we evaluate the lessons learned from data collection during procedural sedation in major hospitals

Methods

- As part of a quality improvement initiative (QII) hospitals collected data on current practice and also after introduction of capnography
- The world SIVA tool[3] was used to define adverse events and interventions of interest
- Simple tools were developed to capture:
  - ASA risk
  - Sedative used
  - Depth of sedation
  - Escalation of care
  - Patient death
  - Identified adverse events
  - Interventions applied
- Proof-of-principle used an offline Excel tool that was later developed into an iPad app (**Fig.1**)

Conclusion

- Digital technology may lower the barrier for real-world data collection
- For medical devices, real-world data collection may:
  - Increase their evidence base
  - Help hospitals to understand the incremental benefits provided by new health

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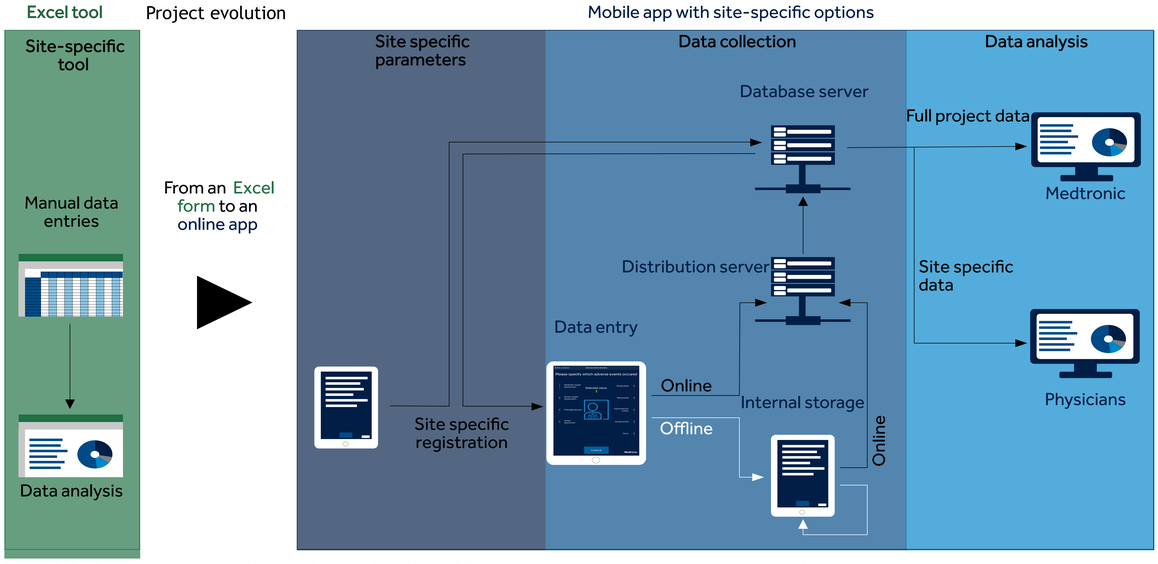

Fig.1 Workflow and evolution of data collection. All online data transfers are encrypted

Results

- Four sites have completed and 5 are currently undertaking a QII using the developed tools (**Fig.2**)
- User reception to and uptake of the data collection tools was positive
- Three sites have been analyzed in full
- To date, data on over 5,000 patients has been collected; far larger than any published clinical study
- The uptake of capnography decreased the cumulative incidence of adverse events by at least 20% at each analyzed site
- Overall, a 41.9% reduction was observed (**Fig.3**), suggesting a positive effect on the awareness on respiratory compromise
- The reduction is in line with published literature[4]

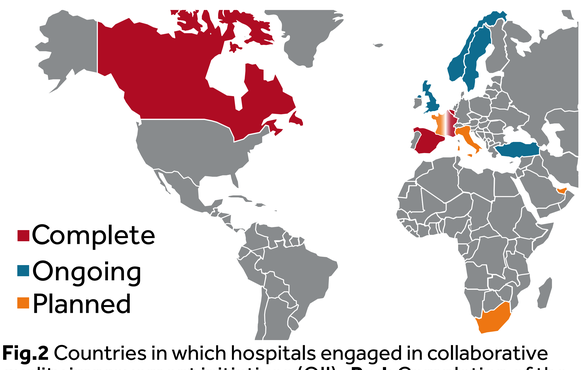

Fig.2 Countries in which hospitals engaged in collaborative quality improvement initiatives (QII) . **Red**: Completion of the QII (Belgium, Canada, France, Spain); **Blue**: Ongoing QII (England, Norway, Sweden, Turkey); **Orange:** Planned QII (France, Italy, South Africa, United Arab Emirates)

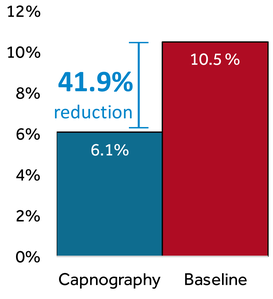

Fig.3 Primary outcome data from all fully analyzed sites (Belgium, Canada, Spain)

Lessons learned

- Success was dependent on the cooperation and buy-in of the medical staff
- Therefore, designing the tools simple and easy-to-use was of paramount importance

References

1. Tarricone R et al.: Health Econ. 2017 Feb;26 Suppl 1:5-12
2. Bernard A et al.: Methodological choices for the clinical development of medical devices. (October):325–34 (2014)
3. Mason KP et al. : Br J Anaesth. 2012 Jan;108(1):13-20
4. Saunders R et al. : BMJ open vol. 7,6 e013402. 30 Jun. 2017

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